K083625

MAR 1 1 2009

Alveolus, Inc.
9013 Perimeter Woods, Suite A
Charlotte, NC 28216, USA

15 510(K) SUMMARY

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS (Per 21 CFR 807.92)

General Company Information

Name:	Alveolus, Inc.
Contact:	Tony Alexander Vice President RA/QA
Address:	9013 Perimeter Woods, Suite A Charlotte, NC 28216
Telephone:	(704) 926 - 4837
Fax:	(704) 926 - 4838

Date Prepared: December 05, 2008

General Device Information

Product Name:	AERO DV™ Tracheobronchial Stent System
Classification:	"Tracheal Prosthesis." Product code: JCT 21 CFR 878.3720 - Class II

Predicate Devices

Alveolus AERO DV™ Tracheobronchial Stent System (510(k) Number: K071604)

Alveolus AERO™ Tracheobronchial Stent System (510(k) Number: K082284)

Rusch International (owned by Boston Scientific) Polyflex Airway Stent (510(k) Number: K013266)

Description

The Alveolus AERO DV™ Tracheobronchial Stent System described in this Notice consists of the exact same stent as the AERO™ predicate stent (K082284) but with an alternate delivery system.

The Direct Visualization (DV) delivery system of AERO DV™ allows the physician to use a bronchoscope to directly view the stent as it is being positioned and deployed at the target implant site. This direct visualization is made possible with a slightly larger delivery catheter lumen that allows passage of a flexible bronchoscope through the delivery catheter.

Intended Use (Indications)

The AERO DV™ Tracheobronchial Stent System is indicated for use in the treatment of tracheobronchial strictures produced by malignant neoplasms.

Substantial Equivalence

This Notice supports the position that the Subject Device is substantially equivalent to AERO DV™ Tracheobronchial Stent System predicate device (K071604). The stent used with the delivery system is the exact same stent cleared under 510(k) K082284.

This 510(k) Notice contains summaries of physical test results for the delivery system as specified in the FDA "Guidance for the Content of Premarket Notifications for Esophageal and Tracheal Prostheses" document (April 28, 1998).

The data presented demonstrate that the device is suitable for its indicated use.

The single-patient-use components of the AERO DV™ Tracheobronchial Stent System are provided non-sterile.

Conclusions

In summary, the Alveolus AERO DV™ Tracheobronchial Stent System described in this Notice has the same stent as the AERO™ predicate stent (K082284), is made of materials that have met the biocompatibility requirements of FDA "Guidance for the Content of Premarket Notifications for Esophageal and Tracheal Prostheses" document (issued on April 28, 1998), has the same indications for use, and has the same principle of operation as those of the AERO DV™ Tracheobronchial Stent System predicate device (K071604). Therefore, the AERO DV™ device does not raise any new issues regarding safety and effectiveness. Therefore, Alveolus believes that the

system is substantially equivalent to currently marketed tracheobronchial stent systems.

The test data provided in this Notice shows that the Subject Device is substantially equivalent to the AERO DV™ Tracheobronchial Stent System predicate (K071604). The AERO DV™ Tracheobronchial Stent System has been tested in accordance with applicable FDA guidelines.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 1 2009

Mr. Tony Alexander
Executive Vice President
Alveolus, Incorporated
9013 Perimeter Woods Drive, Suite A
Charlotte, North Carolina 28216

Re: K083625
Trade/Device Name: Alveolus, AERO DV™ Tracheobronchial Stent Technology System
Regulation Number: 21 CFR 878.3720
Regulation Name: Tracheal Prosthesis
Regulatory Class: II
Product Code: JCT
Dated: February 25, 2009
Received: March 2, 2009

Dear Mr. Alexander:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the device's labeling immediately following the Indications for Use section, and on the carton pouch labeling in a font-size that is easy to read:

If you desire specific information about the application or other labeling requirements to your device (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0100. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Christy Foreman for

Donna-Bea Tillman, Ph.D., M.P.A.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

12 INTENDED USE STATEMENT

Device Name: Alveolus, AERO DV™ Tracheobronchial Stent System

Indications for Use:

The AERO DV™ Tracheobronchial Stent System is indicated for use in the treatment of tracheobronchial strictures produced by malignant neoplasms.

Prescription Use___X___ **AND/OR** **Over-The-Counter Use_____**
(Part 21 CFR 801 Subpart D) **(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K083625